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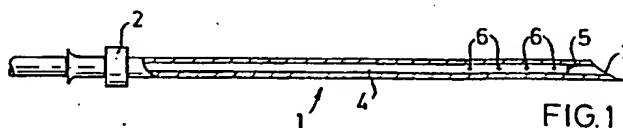
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54 An instrument for the treatment of sinusitis.

57 An instrument for treating sinusitis enabling the introduction of one end of a plastic tube into a maxillary sinus and anchoring it there for successive irrigations distributed over a period of time. Said end of the plastic tube (4) is provided with an arcuate bend for securing after introduction. Introduction is made by entering the tube into the lumen of a cannula (1), whereby the arcuate bend is elastically straightened. The sharp end (3) of the cannula (1) is introduced into the sinus, and the tube is then slid out with its said end into the sinus and regains its arcuate bend for securing, and the cannula is removed, the plastic tube securely remaining until purposely removed.



The present invention regards an instrument useful for the treatment of sinusitis, and particularly useful for repeated irrigations for treating maxillary sinusitis. More particularly, it regards an instrument for the treatment of sinusitis comprising tube means provided with a sharp end for piercing and making a hole in tissue for entering a cavity, and a plastic tube provided for entering one end thereof into said cavity through said tube means, said one end being provided with anchoring means for removably securing said one end within said cavity, said securing means comprising means for forming said one end into a shape incompatible with said hole.

One of the most important and efficient known methods for treating maxillary sinusitis is the drainage of purulent secretion, by means of introducing a liquid through a catheter or the like, which is introduced into the sinus, whereby the liquid and pus may exit through the existing natural lument (ostium).

It is often necessary to renew this operation, which is unpleasant and painful particularly due to the introduction of a cannula through bone, albeit made under local anesthesia. Therefore, instruments have been constructed where an introduced tube may be left for renewed irrigation through the same hole made in the tissue. Another reason why this is desirable is that it is advantageous to provide ventilation of the sinus when its ostium is obstructed by inflammation of the mucus.

One instrument used for this purpose is the Foley catheter (see Abdel-Salam & Gibb, J. Laryngology and Otology 95(1981) 221-223). A trocar is used for introducing a catheter which at its end is provided with an inflatable balloon for retention. In order to inflate the balloon, the catheter

must be provided with a special lumen used only for this purpose, beside the lumen used for irrigation. Therefore, the catheter and the trocar must have a rather large diameter, making a correspondingly large hole.

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Another known instrument comprises a catheter tube provided at its end with wings which at introduction are folded together but which will fold out, roughly into a T-form after introduction by means of a trocar (see Illum & Jepsen, Acta Otolaryngol. 73 (1972) 506-512). Also this  
10 instrument needs a trocar of relatively large diameter, due mainly to the fact that the wings are obtained by cutting the tube, and therefore, the tube cannot be of very small diameter.

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Although the known instruments can be kept in place for subsequent irrigations, (they both have anchoring means which tend to disturb venting mainly due to their size and form) it would be desirable to keep the mucous membrane  
20 as mechanically undisturbed as possible during the time when the catheter is left in place, which may be for several days. Further, it would be desirable to have a round, soft form likely not to disturb even used in cavities of different size and form, and which is not likely  
25 to blow out when a patient sneezes.

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It is therefore a first object of the invention to obtain an instrument permitting the insertion of a securable catheter by means of a piercing instrument having a diameter as small as possible. It is a second object to be  
35 able to obtain an anchorable catheter having anchoring means that are less voluminous and less prone to disturb mucous tissue than what has been the case in the prior art. A third object is to obtain an inexpensive but versatile instrument.

Those objects and other objects and advantages are obtained, according to the invention, by providing an instrument of the kind mentioned in the introduction, wherein the anchoring means comprise an arcuate bend at one end of the plastic tube when free, which bend is elastically stretched out when kept in the tube used for its introduction. This end, when let free inside the cavity, will reform its arcuate bend, which serves as an anchoring means. When positively drawn out of its hole, it will straighten out and can be pulled out after the end of treatment of the patient.

For easy manufacture, it is suitable to form the arcuate bend as a helix. The plastic tube end may then be wound a couple of turns on to a mandrel and be given a permanent tendency to keep its form by suitable heat treatment.

It is also suitable to form the end of the plastic tube as a spiral bend, e.g. in a plane perpendicular to the general direction of the tube. This will give a particularly gentle distributed anchoring likely to give minimum strain to the mucus inside the cavity.

It is preferred to utilize a plastic tube of the kind provided with X-ray absorbent matter, as this gives considerable ease in X-ray explorations.

For maximum irrigation efficiency, it is preferred to provide the arcuate portion of the plastic tube with several openings, from which irrigation liquid may exit. This also tends to improve ventilation between irrigations, as probably not all the openings will be obstructed by pus.

The invention will now be further described in relation to non-limiting embodiments thereof. Fig 1 shows a par-

tially sectioned cannula provided with a straightened plastic tube. Fig 2 shows a plastic tube set free, showing an example of an anchoring configuration. Fig. 3 shows another example of an anchoring configuration.

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The partially sectioned view of Fig 1 shows a cannula 1, provided with a standard Luer-Lok<sup>(R)</sup> fitting 2 at one end and a sharp cutting edge 3 at the other end. Inside the cannula is a plastic tube 4 having, beside its end hole 5, several side openings 6. Although naturally not visible in Fig 1, where the plastic tube 4 is everywhere straight, its material is internally tensioned so that when brought out of the lumen of the cannula, the form of its end will bend into a form susceptible to its anchoring in a cavity when entered by means of the cannula. Thus, when used, the cannula is pierced through a tissue wall of a cavity, and then, the tube 4 is moved out through the lumen and exits at 3. The cannula may be drawn back and removed, leaving the plastic tube in place. The end of this tube then takes an arcuate bend, exemplified in Figs 2 and 3. Many forms are possible for the arcuate bend.

The bend as of Fig 2 is obtained by rolling the plastic tube over a suitable mandrel and held there during successive heating and cooling cycles, whereby the tensions created by rolling are evened out, such that the arcuate form becomes permanented.

When mounting the tube 4 within the cannula 1, this is best performed by entering the tube 4 from the pointed end 3. In order to facilitate this, the end of the lumen should be deburred at its inner edge, as otherwise, its edge may damage the plastic tube 4, particularly when the arcuate form is drawn in.

In order to make the holes 6 in the tube 4, it has been found suitable to burn them by means of a laser ray. This may be done before bending. If made before bending, the holes may be placed at will and also easily on concave sides of the arcuate portion.

According to a tested example, the cannula was of stainless steel with an outer diameter of 2,5 mm and an inner diameter of 2,1 mm, together with a plastic catheter having an outer diameter of 1,8 mm and an inner diameter of 1,5 mm. The overall length of the cannula was 11 cm.

The plastic catheter was made by taking a length of polyethylene ("Tygon"), the middle of which was wound about six turns around a mandrel having a circular form and a diameter of about 6 mm. The mandrel was dipped alternatively in near-boiling water (98°C) and in ice water three times in succession, whereby the deformation was made permanent. The helix portion was then cut off at the middle, creating two catheters. The holes had been made in the tube beforehand.

It is preferred for hygienic reasons to condition the instrument of the invention as a disposable unit. In order to facilitate its practical use, it may be packed together with plastic sacks filled with a suitable irrigation liquid and provided with suitable means for fitting to the protruding end of the anchored plastic tube.

After insertion, the anchored plastic tube may, after a first irrigation, be cut off a short length outside the nostril, such that it may be pushed into the nostril and out of view until next irrigation. The patient may thus be under polyclinical treatment, often making hospitalization unnecessary.

## CLAIMS

1. An instrument for the treatment of sinusitis comprising tube means provided with a sharp end for piercing and making a hole in tissue for entering a cavity, and a plastic tube provided for entering one end thereof into said cavity through said tube means, said one end being provided with anchoring means for removably securing said one end within said cavity, said securing means comprising means for forming said one end into a shape incompatible with said hole, characterized in that said anchoring means comprise an arcuate bend at said one end of the plastic tube when free, said one end of the plastic tube being elastically straightened out when residing in said tube means.

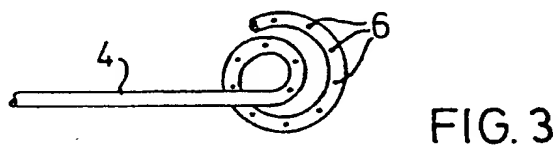
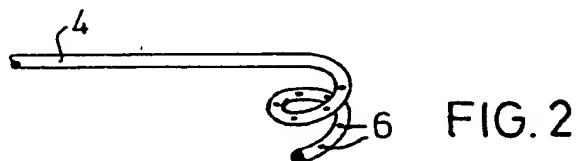
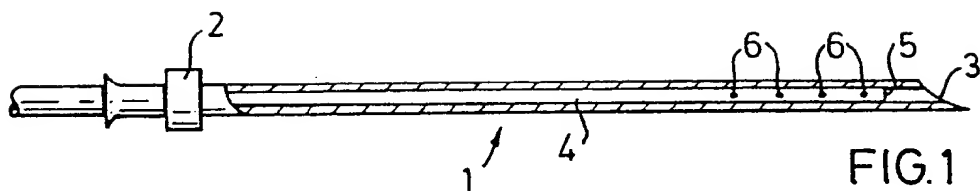
2. The instrument of claim 1, further characterized in that said arcuate bend is a helical bend.

3. The instrument of claim 1, further characterized in that said arcuate bend is a spiral bend.

4. The instrument of claim 1, further characterized in that the plastic tube is made of a material comprising X-ray absorbent matter.

5. The instrument of claim 1, further characterized in that said one end of the plastic tube is provided with several side openings.

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European Patent  
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# EUROPEAN SEARCH REPORT

0129634

Application number

EP 83 85 0180

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 3)
X	BE-A- 893 679 (WILDEMEERSCH) * Page 6, line 27 - page 7, line 12; page 8, lines 11-22; page 9, lines 22-26; page 12, lines 7-17; figures 1-4 *	1,3,5	A 61 M 25/00
Y	US-A-4 068 659 (MOOREHEAD) * Column 4, lines 4-63; column 5, lines 10-15; figure 2 *	1-5	
Y	US-A-3 860 006 (PATEL) * Column 3, lines 33-58; figure 1 *	1,3,4	
Y	US-A-3 924 633 (COOK) * Abstract; figure 3 *	2,5	
A	GB-A-2 018 600 (FINNEY)		TECHNICAL FIELDS SEARCHED (Int. Cl. 3)  A 61 M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 29-12-1983	Examiner GERMANO A.G.
<b>CATEGORY OF CITED DOCUMENTS</b>			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons  & : member of the same patent family, corresponding document	

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